
चिकित्सीय वस्त्रादि — सेलूलोज़
वैडिंग — विशिष्टि

Medical Textiles — Cellulose
Wading — Specification

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FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Technical Textiles for Medtech Applications Sectional Committee had been approved by the Textiles Division Council.

The composition of the Committee responsible for the formulation of this standard is given in Annex C.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

MEDICAL TEXTILES — CELLULOSE WADDING — SPECIFICATION

1 SCOPE

This standard specifies the requirements of cellulose wadding intended for medical use.

2 REFERENCES

The standards listed in Annex A contain provisions, which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated in Annex A.

3 TERMS AND DEFINITIONS

For the purposes of this standard, the following terms and definitions shall apply:

3.1 Cellulose Wadding — Cellulose wadding consists of compressed sheets of felted fibres, consisting almost entirely of cellulose. The fibres are bleached good white.

4 WORKMANSHIP AND FINISH

4.1 The wadding shall be clean and free from substances liable to cause tendering during storage.

4.2 The manufacture and preparation of the waddings shall be conducted under proper hygienic conditions.

5 REQUIREMENTS

5.1 The cellulose wadding shall conform to the requirements specified in Table 1.

5.2 Biocompatibility Evaluation—Cytotoxicity, Irritation and Skin Sensitization

The manufacture shall ensure that raw material used for manufacturing the final product are safe for user based on its known toxicological characteristics at intended use. The biocompatibility of the material shall be detected by evaluating cytotoxicity, irritation and skin sensitization test as per IS/ISO 10993 Part 5 and IS/ISO 10993 Part 10 respectively.

For cytotoxicity, the material shall show reactivity as “None” when tested as per IS/ISO 10995 Part 5. Similarly, the material shall be “Non-irritant and Non-sensitizer” when tested as per IS/ISO 10993-10. For preparation of samples for these tests, ISO 10993-12 shall be referred.

6 MARKING

6.1 Each pack of the cellulose wadding shall be legibly marked with the following information:

- a) Name of the product;
- b) Manufacturer’s name, initials or trade-mark, if any;
- c) Month and year of manufacture;
- d) Batch/Lot No.;
- e) Dimensions; and
- f) Any other statutory requirement as required by the law in force

6.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity

Table 1 Performance Requirements for Cellulose Wadding

(Clause 5.1)

Sl No.	Characteristic	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Fibre identification	complies with test	IS 14944
ii)	Weight per square metre, (g/m ²)	425 to 550	IS 1964
iii)	Absorbency (Sinking Time), s, <i>Max</i>	9	IS 14944
iv)	Loss on drying, percent, <i>Max</i>	10	when determined on 5 g sample by drying in an oven at 100-105 °C for 1 h
v)	Chloroform soluble substances, percent, <i>Max</i>	1.0	Annex B
vi)	Sulphated ash, percent, <i>Max</i>	0.45	IS 14944
vii)	Fluorescence	Examine a layer about 5 mm in thickness under ultra-violet light (365 nm) the wadding displays only a slight brownish violet fluorescence and few yellow particles. Not more than a few isolated fibers show an intense blue fluorescence.	

assessment schemes under the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

7 SAMPLING AND CRITERIA FOR CONFORMITY

7.1 Lot

All the cellulose waddings of the same material, shape and dimensions produced under similar conditions of manufacture shall constitute a lot.

7.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

7.1.2 The number of cellulose waddings to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 2, 3 and 5 of Table 2.

7.1.3 These waddings shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

NOTE — for biocompatibility evaluation refer 7.2.4.

7.2 Number of Tests and Criteria for Conformity

7.2.1 All waddings selected as per column 3 of Table 2 shall be examined for workmanship and finish (*see 4.1*).

7.2.1.1 Any wadding failing in one or more of the above requirements shall be termed as defective. The

lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 4 of Table 2. Otherwise, the lot shall be rejected.

7.2.2 Out of the sample already found satisfactory according to 7.2.1.1, a sub-sample as per column 5 of Table 2 shall be taken. This sub-sample shall be further tested for the remaining requirements.

7.2.3 The lot shall be considered as conforming to the requirements of the specification, if the total number of defective waddings found in the sample (*see 7.2.2*) is less than or equal to the acceptance number as given in column 6 of Table 2.

7.2.4 The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply of raw material for manufacturing the product.

8 PACKING

The cellulose wadding shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Details of the packing shall be as agreed to between the buyer and the seller. Packaging of the product shall be such as to maintain the integrity of the product throughout its shelf life.

Table 2 Number of Cellulose Waddings to be Selected

(Clause 7.1.2, 7.2.1, 7.2.1.1, 7.2.2 and 7.2.3)

Sl No.	Lot Size	Non-Destructive Testing		Destructive Testing	
		No. of waddings to be Selected	Acceptance Number	No. of waddings to be Selected	Acceptance Number
	N	n	a	n_1	a_1
(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 280	13 ¹⁾	1	8	0
ii)	281 – 500	20	2	8	0
iii)	501 – 1 200	32	3	13	0
iv)	1 201 – 3 200	50	5	13	0
v)	3 201 – 10 000	80	7	20	1

¹⁾ Or lot size when less than 13.

ANNEX A

(Clause 2.1)

LIST OF REFERRED INDIAN STANDARDS

<i>IS No.</i>	<i>Title</i>	<i>IS No.</i>	<i>Title</i>
1964 : 2001	Method for determination of mass per unit length and mass per unit area of fabrics (<i>second revision</i>)	IS/ISO 10993 (Part 5) : 2009	Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity
4905 : 2015	Random sampling and randomization procedures (<i>first revision</i>)	IS/ISO 10993 (Part 10) : 2010	Biological evaluation of medical devices: Part 10 Tests for irritation and skin sensitization
14944 : 2001	Surgical dressings — Methods of test	ISO 10993-12 : 2012	Biological evaluation of medical devices: Part 12 Sample preparation and reference materials

ANNEX B[Table 1, *Sl No.* (v)]**METHOD FOR DETERMINATION CHLOROFORM SOLUBLE SUBSTANCES**

B-1 Extract 5 g with chloroform in a Soxhlet apparatus for 4 h, operating the apparatus in such a manner that the rate is at least four extractions per hour. Evaporate the ether extract and dry the residue to constant weight at 100 to 105 °C, unless specified otherwise in the standard.

ANNEX C

(Foreword)

COMMITTEE COMPOSITION

Technical Textiles for Medtech Applications, TXD 36

<i>Organization</i>	<i>Representative(s)</i>
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KOB Medical Textiles Pvt Ltd, Palladam	SHRI ARUN BUCHADE SHRI S. KUMAR SUBRAMANIAN (<i>Alternate</i>)
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